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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,213	04/19/2004	Nicola Lucia Pohl	P06218US01	2894

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DES MOINES, IA 50309-2721

EXAMINER

MAIER, LEIGH C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/827,213	Applicant(s) POHL ET AL.	
	Examiner Leigh C. Maier	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 9-21 and 25-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/16/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restriction

Applicant's election without traverse of Group I, claims 1-8 and 22-24 in the reply filed on November 28, 2005 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite the term "analog," but it is not clear what Applicant feels constitutes an "analog." For example, claim 2 recites "a C-glycoside analog of isopropyl- β -D-thiogalactoside (IPTG)." Applicant's preferred embodiment is isobutyl- β -C-galactoside. This compound is a fairly strict structural analog, with only the sulfur being replaced by a methylene group. All other structure and stereochemistry remains the same. Because the claim depends from claim 1, the compounds embraced by this claim must be effective in inducing expression of proteins, etc. However, with regard to structure, it is not clear what, if anything, other than a C-glycoside moiety, is required.

Claim 3 recites "[a] C-glycoside analog of IPTG." Claim 4, depending from claim 3, recites the C-glycoside "that is functionally equivalent to IPTG." This brings up the question, is

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claim 4 any different in scope than claim 2? A compound embraced by claim 2 must be a C-glycoside effective in inducing expression of proteins. Is a compound that is “functionally equivalent” to IPTG required to have functionality other than protein induction? If so, it is not clear what it might be.

Claim 5 recites “the recombinant proteins,” but this limitation has no antecedent basis.

Claim 7 appears to improperly broaden the scope of claim 2. Claim 2 requires effectiveness in inducing protein expression. However, claim 7 allows for analogs, optical isomers, etc. It does not appear to require that all these various analogs and isomers also have utility in inducing protein expression. See discussion below.

Due to the uncertainties in claim interpretation, one of ordinary skill would not be apprised of the metes and bounds of the invention.

Claims 1-8 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

- (1) The quantity of experimentation necessary (time and expense);
- (2) The amount of direction or guidance presented;
- (3) The presence or absence of working examples of the invention;
- (4) The nature of the invention;
- (5) The state of the prior art;
- (6) The relative skill of those in the art;
- (7) The predictability or unpredictability of the art; and
- (8) The breadth of the claims.

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The claims are drawn to “a compound that is effective in inducing expression of proteins under control of a lac-based promoter, said compound being stable at ambient temperatures.”

The specification appears to be enabled for β -C-galactosides, but not the full range of compounds commensurate in scope with the invention as claimed. It is known that promoters typically have a structure that is similar to lactose, wherein the glucose moiety is replaced by another chemical group, and the compound retains β -linkage at the anomeric carbon. See, for example, the Wikipedia entry for “Lac-operon.” http://en.wikipedia.org/wiki/Lac_operon - retrieved 12/22/05. As noted above, the claims appear to embrace a large number of non-galactose C-glycosides. Based on what is known in the art, it seems unlikely that these non-galactose products would be effective in inducing expression of proteins under control of a lac-based promoter, and Applicant has disclosed no evidence of activity for non-galactose products. Furthermore, with regard to stereochemistry at the anomeric carbon, in Applicant’s preferred embodiment, isobutyl-C-galactoside, Applicant describes the need to separate the α - and β -isomers. In doing so, Applicant essentially admits that only the β -isomer—as would be expected from what is known in the art—is active in the described utility.

Therefore in view of the foregoing, it would appear that one of ordinary skill would require undue experimentation in order to use the claimed product commensurate in scope with the claims.

For the purposes of claim amendments, it is noted that the examiner does not find support for a generic claim to novel β -C-galactosides.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, and 22-24 rejected under 35 U.S.C. 102(b) as being anticipated by Baneyx (Curr. Opin. Biotechnol., 1999) with USB product description “IPTG Dioxane Free” (<http://www.usbio.net/Product.aspx?ProdId=108> -- retrieved 12/22/05) to demonstrate inherency.

Baneyx teaches that IPTG has utility for induction of protein expression under control of a lac-based promoter. See “Promoters” section at page 412. The USBiological data sheet for IPTG discloses that the compound is stable at room temperature. See “Storage and Stability.”

Regarding claim 7, the claim includes analogs of IBCG. The specification identifies IBCG as an analog of IPTG. Therefore, IPTG must in turn be an analog of IBCG.

Claims 3, 7, and 8 rejected under 35 U.S.C. 102(b) as being anticipated by Marquez et al (Anales de Quimica, 1983).

Marquez discloses compound I-10. See Figure 1 and Table III. The compound appears to be a structural analog of both IPTG and IBCG. Neither of these claims requires any particular activity. Regarding claim 8, the specification appears to define the term “isobutyl-C-galactoside,” per se, so that stereochemistry is allowed to vary liberally. See page 4, 1st full paragraph. From this, it would appear that the term embraces the isobutyl-C-glycoside of essentially any monosaccharide.

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Claims 1-7 and 22-24 rejected under 35 U.S.C. 102(b) as being anticipated by Hindsgaul (US 6,174,867).

Hindsgaul discloses a number of C-galactosides. See Figure 1. The reference is silent regarding the recited functional limitations; however, these compounds appear to be embraced by the description of compounds that have said limitations. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Allowable Subject Matter

A claim to isobutyl- β -C-galactoside would allowable. Hindsgaul teaches as set forth above. The reference does not teach or fairly suggest the preparation of this compound. If the decision were made to amend to this allowable product, Applicant would be entitled to rejoinder of the methods of making and methods of using, commensurate with said allowable product. It would appear that the protected product recited in claim 28 would also be allowable.

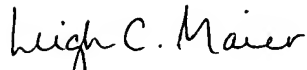
Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 873-8300.

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Leigh C. Maier
Primary Examiner
December 22, 2005